IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA

Alexandria Division

UNITED STATES OF AM	ERICA)
v.)) CRIMINAL NO. 03-530-A
,)
DANIEL M. VARALLI)

STATEMENT OF FACTS

The United States and the defendant agree that had this matter proceeded to trial, the United States would have proven the following facts beyond a reasonable doubt:

1. Defendant DANIEL M. VARALLI was a pharmacist residing in the Commonwealth of Virginia, and licensed in Virginia, Tennessee, Arkansas, Michigan, and South Carolina. From June 1999 through June 2000, VARALLI participated in a conspiracy to sell via the Internet, controlled substances and other prescription drugs to consumers in the United States and throughout the world. Through these methods, the defendant and his co-conspirators massmarketed their drugs and services. In furtherance of this conspiracy, VARALLI distributed and dispensed controlled substances and other prescription drugs to customers, along with other individuals and entities with whom he conspired. VARALLI, as the pharmacist-in-charge of Rx Direct, a pharmacy in Roanoke, Virginia, and as a pharmacist at another Roanoke pharmacy, known as Home Prescription Services, personally distributed and dispensed at least 20,939 controlled substance prescriptions, which resulted in the distribution and dispensing of at least 52,800 pills of Schedule III drugs and at least 1.25 million pills of Schedule IV drugs, all in violation of federal law. Such drugs were distributed and dispensed to customers in, among

other places, Fairfax County, Arlington County, and Fauquier County in the Eastern District of Virginia. During this time period, VARALLI was aware that other pharmacist co-conspirators were also distributing and dispensing controlled substances and other prescription drugs to customers of websites controlled by his co-conspirators.

- 2. A co-conspirator hired VARALLI to distribute and dispense the controlled substances and other prescription drugs to customers who ordered drugs over the Internet from several websites. The websites, which advertised various controlled substances and other prescription drugs for sale to domestic and international customers, were owned and operated by Vincent K. Chhabra, and other co-conspirators. During the course of the conspiracy, VARALLI became a 45% co-owner of Rx Direct, a pharmacy licensed in the Commonwealth of Virginia that was established to fill orders from Internet websites. Sunil K. Sethi, a co-conspirator, reimbursed Rx Direct for the wholesale cost of drugs, and paid Rx Direct a fee for every prescription filled for websites associated with this conspiracy. Sethi forwarded prescriptions to be filled for the Chhabra-related websites to Rx Direct.
- 3. The Schedule III substance distributed and dispensed was phendimetrazine, a stimulant for weight loss, sold by its brand name Bontril. The Schedule IV substances distributed and dispensed were phentermine, sold generically and by the brand names Adipex and Ionamin, and sibutramine hydrochloride, sold by the brand name Meridia. These drugs are indicated for weight loss. Other prescription drugs distributed and dispensed included Viagra, Xenical, Propecia, and Celebrex.
- 4. Customers who ordered drugs from the websites were not required to provide a prescription before receiving the controlled substances. Instead, customers filled out an online

order form and chose the type, quantity, and dosage of controlled substance the customer wished to purchase. Customers also answered questions about their medical conditions.

- 5. The prescriptions were dispensed under the authorizations of Dr. Daniel Thompson, Dr. William Thompson, Dr. Marvin Brown, Dr. Russell Johnson, Dr. Arturo Portales, and Dr. Laurence Cockerille.
- 6. Under the Controlled Substances Act and its implementing regulations, for a prescription to be valid, a prescription has to be issued for a legitimate medical purpose by an individual acting in the usual course of the professional practice. 21 C.F.R. § 1306.04.
- 7. The prescriptions authorized by the physicians were not valid because they did not establish a doctor-patient relationship. Other than the questionnaires, the physicians did not have any contact with the persons ordering the medication. They performed no mental or physical examination, did not take a patient history or perform any diagnostic or laboratory testing, did not check the accuracy of the information customers provided (including their identities, ages, and qualifying medical conditions, such as weight), and did not monitor, or provide any means to monitor, medication response, weight loss or weight gain. Instead, the controlled substances, as set forth above, were distributed and dispensed for other than legitimate medical purposes and not in the usual course of professional practice. As such, VARALLI's and his co-conspirators' actions violated the Controlled Substances Act.
- 8. VARALLI and his co-conspirators distributed and dispensed excessive quantities of controlled substances to particular customers on a regular basis. Additionally, VARALLI distributed and dispensed excessive quantities to particular customers that had been authorized by numerous doctors.

- 9. Distributing and dispensing controlled substances on the basis of a review of an order form, where there is no previously established doctor-patient relationship, can lead to harm to the person ordering drugs.
- 10. VARALLI received a total of \$ 720,000 in wages and profits for distributing and dispensing controlled substances and other prescription drugs ordered by the Internet customers.
- 11. VARALLI used a special skill, his pharmacy training, in order to facilitate the commission of this offense.

Respectfully submitted,

PAUL J. McNULTY UNITED STATES ATTORNEY

By:

James P. Gillis Karen L. Taylor Assistant United States Attorneys

Linda I. Marks
Jill P. Furman
Attorneys
Office of Consumer Litigation
United States Department of Justice

After consulting with my attorney and pursuant to the plea agreement entered into this day between the defendant, DANIEL M. VARALLI, and the United States, I hereby stipulate that the above Statement of Facts is true and accurate, and that had the matter proceeded to trial, the United States would have proved the same beyond a reasonable doubt.

Daniel M. Varalli Defendant I am DANIEL M. VARALLI's attorney. I have carefully reviewed the above Statement of Facts with him. To my knowledge, his decision to stipulate to these facts is an informed and voluntary one.

Barry Coburn Counsel for Defendant